

April 23, 2021

VIA E-MAIL

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**Re: Reply in Support of Petition to Cancel RM Glufosinate-Ammonium
Technical**

The Agricultural Handler Exposure Task Force, LLC (AHETF or the Task Force) submits this Reply in further support of its February 10, 2021 Petition to Cancel Ragan and Massey, Inc.'s (RM) RM Glufosinate-Ammonium Technical (Technical) registration (EPA Reg. No. 84840-3) (originally EPA Reg. No. 84009-34), and to deny or cancel any glufosinate applications or registrations that rely on that registration.

RM's April 9, 2021 Response to AHETF's Petition fails fundamentally in its assertion that RM can rely on Pesticide Handler Exposure Database ("PHED") data in lieu of AHETF data for the five occupational exposure handler scenarios identified in AHETF's Petition. *See* Petition at 5. R&M's Response is further flawed for these critical reasons:

- EPA must have proper, current, and valid data when it makes fundamental decisions on whether the exposure data requirements are satisfied when evaluating and determining whether to register a pesticide product. It is in this context that the Agency notes on its website that "as AHETF data for each pesticide handler exposure scenario becomes available, they will supersede existing data."¹

¹ <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#ahetf>.

- RM must cite the 35 studies related to the following five exposure scenarios identified in AHETF's Petition: (1) mixing/loading of liquids; (2) application aerially; (3) application with ground boom equipment; (4) mixing/loading/application with mechanically pressurized handgun sprayers; and (5) mixing/loading/application with backpack sprayers. *See* AHETF Petition at 5-6. All 35 studies supporting these five scenarios have been reviewed and accepted by EPA, and have supplanted PHED data.
- Contrary to R&M's assertions, AHETF's data are not crop-based – they are activity-based. AHETF recognizes that RM's technical is not registered for crop uses. As discussed further below, AHETF's data supporting mixing, loading, and applying pesticides are equally applicable to the non-crop uses on RM's label to crop uses.
- A major reason AHETF data are replacing PHED data is because EPA required AHETF to undertake an extraordinarily expensive set of studies in compliance with Human Studies Review Board (HSRB) requirements, so that the AHETF data now available to support mixing, loading, and application activities represent the best available science. It would fly in the face of this effort for EPA to allow a company to rely upon the old, discredited PHED data as an alternative.
- EPA has recognized that the AHETF database, compared to PHED, has a “robust statistical design and improved analytical methods, and is representative of current handling techniques,” providing to prospective registrants a much sounder basis to demonstrate exposures to their products than the PHED database, and thus there are significant benefits to both the industry and EPA in being able to rely upon AHETF data.²
- Over 60 companies have either joined or reached agreements with AHETF to cite its data and many of these companies are generic pesticide manufacturers like RM. It would completely undercut the integrity of these industry-wide Task Forces to allow a company to ignore the current data requirements when it chooses to cite instead of submit its own data.

AHETF provides further support for these propositions below.

I. AHETF Data are Required to Support RM's Selective Citation

RM's Response spends a significant amount of time arguing that AHETF's position is that RM should cite all AHETF data. Contrary to RM's assertions, AHETF does not treat RM's selective citation application as if it were a cite-all application. AHETF filed its Petition because RM failed to meet the fundamental selective-method mandate of 40 C.F.R. § 152.90 to submit or

² <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#ahetf>.

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cite data to demonstrate compliance with an applicable data requirement – the human exposure data required pursuant to 40 C.F.R. § 158.1020. EPA has reviewed and accepted AHETF data for numerous exposure scenarios, including the five listed in Part II.A. of AHETF’s Petition and which are supported by the 35 studies that RM should have been required to cite for its registration as set forth in AHETF’s Petition.

If EPA fails to require AHETF data in this instance, EPA will be completely undermining its clear determination that AHETF data has replaced PHED data for these scenarios and that AHETF data are the current data requirement. Permitting the sale and marketing of a product which is not supported by the current occupational exposure handler data requirements but relies on an outdated database would be a fundamental error by the Agency, particularly when EPA explicitly endorsed AHETF’s activity in PR Notice 2007-3.³ This would open the door for abuse of the selective method process and would lead to increased disputes between the Task Force and follow-on registrants, to the detriment of both the EPA program and the Task Force’s work. Absent a complete and unqualified offer to pay from RM, EPA must cancel RM’s registration.

II. RM Must Cite AHETF Data to Support Non-crop Uses

AHETF’s Petition acknowledges that the RM Glufosinate-Ammonium Technical registration allows it to be formulated into an herbicide for: “weed control of emerged weeds in non-crop areas, control of weeds and grasses in residential and industrial areas.” Petition at 2-3. Contrary to RM’s argument, AHETF’s 35 studies support these five exposure scenarios, have superseded PHED data, and are required for non-crop as well as crop uses.

As noted above, EPA’s occupational handler exposure data requirements, as set forth in EPA’s Surrogate Reference Table, are imposed based on activity, not based on crop use patterns. This concept is explicitly set forth in the applicator exposure data requirements table at 40 C.F.R. § 158.1020, which includes both crop and non-crop uses in “occupational use patterns.”⁴ Consistent with this, the Surrogate Reference Table identifies exposure scenarios by “activity, equipment, formulation, site, etc.” and not by crop or non-crop use.⁵ Footnote 1 of the Surrogate

³ EPA Pesticide Registration Notice 2007-3: The Agricultural Handlers Exposure Task Force, LLC (PR Notice 2007-3), <https://www.epa.gov/pesticide-registration/prn-2007-3-agricultural-handlers-exposure-task-force-llc>.

⁴ “Occupational use patterns include products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, terrestrial nonfood crop, aquatic food, aquatic nonfood use, forestry, greenhouse food, greenhouse nonfood, indoor food use, and indoor nonfood use. Occupational use patterns also include commercial (‘for hire’) applications to residential outdoor and indoor sites.” 40 C.F.R. § 158.1020.

⁵ <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/exposure-surrogate-reference-table-pesticide-risk>.

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Reference Table notes, “[i]f the description of the scenario is silent on specific equipment, sites, formulations, etc., the data are applicable to all potential applications for that scenario.”⁶

That AHETF data applies equally to crop and non-crop uses is explicit on the Surrogate Reference Table. For example, EPA describes the mixer/loader/applicator, mechanically-pressurized handgun sprayer scenario as pertaining to among other things, specialty agricultural crops and industrial/commercial areas. Surrogate Reference Table at 6-7. The same AHETF data applies equally for both these use sites.

As set forth in AHETF’s Petition, RM’s technical registration is labeled for mixing/loading of a liquid and application either aerially, by ground boom, mechanically-pressurized handgun sprayer, and/or backpack sprayer.⁷ EPA should require RM to cite each of the AHETF studies supporting these scenarios as set forth in AHETF’s Petition.

III. EPA Has Replaced PHED Data with AHETF Data for the Occupational Exposure Data Requirements on which RM Relies

EPA has frequently recognized the deficiencies with PHED, and that AHETF data are now being used to satisfy occupational exposure data requirements. AHETF refers EPA to the following:

- In the minutes from EPA’s January 2007 FIFRA Scientific Advisory Panel (“SAP”) meeting, EPA recognizes that “scientific issues have been raised about the accuracy of exposure estimates,” with PHED, and that PHED data does not incorporate recent protocols generated by EPA’s Human Studies Review Board (“HSRB”). The SAP listed several deficiencies within PHED including “inconsistent data quality; a patch-work of methods, some with high uncertainty and data censoring; a high level of ‘clustering,’ and an inadequate number of

⁶ *Id.*

⁷ RM erroneously claims that “MRID Nos. 46763702, 47212801, 47309201, 47309202, 47309203 and 4730903 [sic]” are not applicable because these studies use crops, turf, greenhouses, or orchards as use sites. These AHETF data support all occupational use exposure scenarios for mixing/loading liquids (MRID Nos. 46763702, 47212801, 47309201, 47309202, 47309203), aerial – enclosed cockpit (MRID No. 46763702), and open cab groundboom (MRID Nos. 47309201, 47309202, 47309203). All of these exposure scenarios are present on RM’s label.

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samples and diversity within some scenarios.”⁸ AHETF data both addresses these deficiencies, and unlike PHED, were subject to extensive HSRB review.

- As EPA states in PR Notice 2007-03, the SAP “confirmed the need for new handler exposure studies and generally supported the methods proposed by the AHETF for conducting these studies,” concluding that “[t]he data generated by the AHETF are expected to provide EPA with significantly better information than it now has for assessing handler exposure.”⁹ AHETF data has met this expectation, leading EPA to systematically replace PHED data with AHETF data as it is reviewed and accepted by EPA.

EPA should not allow RM to retain its registration unless RM promptly satisfies all of the applicable data requirements by citing and offering to pay AHETF, at a minimum, for the 35 required studies identified in AHETF’s Petition. These data are required to support the five labeled use scenarios supported by these AHETF data and EPA should, at this time, confirm that these data must be cited.

Thank you for your consideration.

Respectfully submitted,



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⁸ Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held January 9 - 12, 2007 on the Review of Worker Exposure Assessment Methods (April 2, 2007), at 4, 7, <https://archive.epa.gov/scipoly/sap/meetings/web/pdf/january2007finalmeetingminutes.pdf>.

⁹ See PR Notice 2007-3.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 23rd day of April, 2021, true and correct copies of the foregoing Reply in Support of Petition to Cancel RM Glufosinate-Ammonium Technical was served upon the following by e-mail:

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